

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: William HARRIS *et al.*

Serial No.: Unassigned

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Examiner: Unassigned

For: POLYETHYLENE HIP JOINT PROSTHESIS WITH EXTENDED RANGE OF MOTION

**Preliminary Amendment**

**This application is a continuation of PCT/US99/16070**

Commissioner of Patents  
Washington, DC 20231

Dear Sir:

Before action by the Examiner, please amend the captioned application as set forth below.

**In the Specification**

Page 1, lines 6-11, please replace the entire paragraph with  
-- This application is a continuation of PCT/US99/16070, filed July 16, 1999, the entirety of which is hereby incorporated by reference. --

**In the Claims**

Please cancel Claims 2-36 without prejudice or disclaimer and add the following Claims:

37. (new) A surface replacement hip joint prosthesis comprising:
  - a. an acetabular cup that includes a load bearing portion and can embrace a femur cup; and
  - b. a femur cup that has a mating portion and defines a cavity that accommodates a femur head;

wherein at least part of the acetabular cup and femur cup comprise cross-linked ultra high molecular weight polyethylene (UHMWPE), wherein the thickness of the cross-linked UHMWPE of the acetabular cup and femur cup are greater than about 1 mm.

38. (new) The prosthesis of claim 37, wherein the thickness of the cross-linked UHMWPE of the acetabular cup and femur cup are between about 1 mm to about 5 mm.

39. (new) The prosthesis of claim 37, wherein the thickness of the cross-linked UHMWPE of the acetabular cup and femur cup are between about 5 mm to about 8 mm.

40. (new) The prosthesis of claim 37, wherein the thickness of the cross-linked UHMWPE of the acetabular cup and femur cup are between about 8 mm to about 10 mm.

41. (new) The prosthesis of claim 37, wherein the femur cup is metallic.

42. (new) A surface replacement hip joint prosthesis assembly comprising:

- a metallic acetabulum shell, wherein the shell can be fixed to the pelvis to be disposed to be in contact with an acetabular cup;
- an acetabular cup that includes a load bearing portion and can embrace a femur cup; and
- a femur cup, that has a mating portion and defines a cavity that accommodates a femur head;

wherein at least part of the acetabular cup and femur cup comprise cross-linked ultra high molecular weight polyethylene (UHMWPE), and wherein the thickness of the cross-linked UHMWPE of the acetabular cup and femur cup are greater than about 1 mm.

43. (new) A hip joint prosthesis comprising:

- an acetabular cup that includes a load bearing portion and can embrace a ball head, wherein the cup comprises cross-linked UHMWPE,

and wherein the thickness of the cross-linked UHMWPE of the acetabular cup is greater than about 1 mm; and

b. a ball head which has a radius of curvature complementary to the cavity in the acetabular cup, wherein when the ball head can be embraced by the said acetabular cup forms an articulation to provide motion such that  $\theta_{\max}$  is about 60° or more, and wherein the head diameter is greater than about 35 mm.

44. (new) The prosthesis of claim 43, wherein the thickness of the cross-linked UHMWPE of the acetabular cup is between about 1 mm to about 5 mm.

45. (new) The prosthesis of claim 43, wherein the thickness of the cross-linked UHMWPE of the acetabular cup is between about 5 mm to about 8 mm.

46. (new) The prosthesis of claim 43, wherein the thickness of the cross-linked UHMWPE of the acetabular cup is between about 8 mm to about 10 mm.

47. (new) The prosthesis of claim 43, wherein the thickness of the cross-linked UHMWPE of the acetabular cup is between at least about 10 mm and at least about 20 mm.

48. (new) The prosthesis of claim 43, wherein the ball head diameter is between about 35 mm to about 40 mm.

49. (new) The prosthesis of claim 43, wherein the ball head diameter is between about 40 mm and about 70 mm.

50. (new) The prosthesis of claim 43, wherein the ball head diameter is between about 70 mm and about 90 mm.

51. (new) The prosthesis of claim 43, wherein  $\theta_{\max}$  is about 60° to about 90°.

52. (new) The prosthesis of claim 43, wherein  $\theta_{\max}$  is about 60° to about 70°.

53. (new) The prosthesis of claim 43, wherein the bearing portion has a rim chamfer having an angle  $\theta_c$  which is substantially equal to  $\theta_{\max}$ .

54. (new) The prosthesis of claim 43, wherein the cross-linked UHMWPE of the acetabular cup has a storage modulus of about 850 MPa or less.

55. (new) The prosthesis of claim 43, wherein the cross-linked UHMWPE of the acetabular cup has a contact stress of less than about 10 MPa.
56. (new) The prosthesis of claim 43, wherein the cavity depth is at least about 16 mm.
57. (new) The prosthesis of claim 43, wherein the bearing portion defines a sphere segment cavity and said mating portion is a ball head.
58. (new) The prosthesis of claim 57, wherein the sphere segment is a hemisphere.
59. (new) The prosthesis of claim 57, wherein the sphere segment defines less than a hemisphere in all directions of motion.
60. (new) The prosthesis of claim 57, wherein the sphere segment defines less than a hemisphere in a selected direction of motion and a hemisphere in another direction of motion.
61. (new) The prosthesis of claim 43, wherein the ball head comprises of material selected from a group consisting of: polymer, metal, and ceramic.
62. (new) The prosthesis of claim 43, wherein the head is spherical.
63. (new) The prosthesis of claim 43, wherein the head is ovoid.
64. (new) The prosthesis of claim 57, wherein the mating portion comprises a prosthetic ball member to be attached to the femur.
65. (new) A hip joint prosthesis comprising:
  - a. a metallic acetabulum shell, wherein the shell can be fixed to the pelvis to be disposed to be in contact with an acetabular cup; and
  - b. an acetabular cup that includes a load bearing portion and can embrace a femur cup or a ball head, wherein the acetabular cup comprises cross-linked UHMWPE, wherein the thickness of the cross-linked UHMWPE of the acetabular cup is greater than about 1 mm, and wherein the acetabular cup or the femur cup can accommodate a ball head having a diameter greater than about 35 mm and which has a radius of curvature complementary to the cavity in the acetabular cup or the femur cup.

66. (new) The prosthesis of claim 65, wherein the thickness of the cross-linked UHMWPE of the acetabular cup is between about 1 mm to about 5 mm.
67. (new) The prosthesis of claim 65, wherein the thickness of the cross-linked UHMWPE of the acetabular cup is between about 5 mm to about 8 mm.
68. (new) The prosthesis of claim 65, wherein the thickness of the cross-linked UHMWPE of the acetabular cup is between about 8 mm to about 10 mm.
69. (new) The prosthesis of claim 65, wherein the thickness of the cross-linked UHMWPE of the acetabular cup is between at least about 10 mm and at least about 20 mm.
70. (new) The prosthesis of claim 65, wherein the cross-linked UHMWPE of the acetabular cup has a storage modulus of about 850 MPa or less.
71. (new) The prosthesis of claim 65, wherein the cross-linked UHMWPE of the acetabular cup has a contact stress of less than about 10 MPa.
72. (new) The prosthesis of claim 65, wherein the cavity depth is at least about 16 mm.
73. (new) The prosthesis of claim 65, wherein the acetabular cup defines an internal diameter that accommodates a ball head having a diameter between about 35 mm to about 40 mm.
74. (new) The prosthesis of claim 65, wherein the acetabular cup defines an internal diameter that accommodates a ball head having a diameter between about 40 mm and about 70 mm.
75. (new) The prosthesis of claim 65, wherein the acetabular cup defines an internal diameter that accommodates a ball head having a diameter between about 70 mm and about 90 mm.
76. (new) The prosthesis of claim 65, wherein the acetabular cup can embrace a femur cup defines an internal diameter that accommodates a ball head having a diameter between about 35 mm to about 40 mm.

77. (new) The prosthesis of claim 65, wherein the acetabular cup can embrace a femur cup defines an internal diameter that accommodates a ball head having a diameter between about 40 mm and about 70 mm.
78. (new) The prosthesis of claim 65, wherein the acetabular cup can embrace a femur cup defines an internal diameter that accommodates a ball head having a diameter between about 70 mm and about 90 mm.
79. (new) A hip joint prosthesis assembly comprising:
  - a. a metallic acetabulum shell, wherein the shell can be fixed to the pelvis to be disposed to be in contact with an acetabular cup;
  - b. an acetabular cup that includes a load bearing portion and can embrace a ball head, wherein the cup comprises cross-linked UHMWPE, and wherein the thickness of the cross-linked UHMWPE of the acetabular cup is greater than about 1 mm; and
  - c. a ball head which has a radius of curvature complementary to the cavity in the acetabular cup, wherein when the ball head can be embraced by the said acetabular cup to form an articulation to provide motion such that  $\theta_{\max}$  is about 60° or more, and wherein the head diameter is greater than about 35 mm.
80. (new) The prosthesis assembly according to claim 79, comprises an attachment assembly for attaching the said bearing portion to a patient, wherein the said attachment assembly is selected from a group of materials comprising bone cement, a metal shell, or a combination of bone cement and a metal shell.
81. (new) The prosthesis assembly according to claim 79, wherein the ball head cross-section (HS) satisfies:

$$HS = SS - 2T_c - 2T_s - 2T_L, \text{ wherein}$$

SS is pelvic socket size,

$T_c$  is bone cement thickness,

$T_s$  is shell thickness,

$T_L$  is polymer thickness.

82. (new) The prosthesis assembly of claim 81, wherein HS is about 28 mm or more when SS is about 44 mm or less.
83. (new) The prosthesis assembly of claim 81, wherein HS is about 32 mm or more when SS is about 43 mm or more.
84. (new) The prosthesis assembly of claim 81, wherein HS is about 45 mm or more when SS is about 55 mm or more.
85. (new) The prosthesis of claim 81, wherein  $\theta_{\max}$  is greater than about 60° when HS is greater than 35 mm.
86. (new) The prosthesis assembly of claim 81, wherein  $T_c$  is between about 0 to about 6 mm.
87. (new) The prosthesis assembly of claim 81, wherein  $T_s$  is between about 0 to about 5 mm.
88. (new) The prosthesis assembly of claim 81, wherein  $T_L$  is between about 1 to about 5 mm.
89. (new) A hip joint prosthesis assembly comprising:
  - a. a metallic acetabulum shell, wherein the shell can be fixed to the pelvis to be disposed to be in contact with an acetabular cup; and
  - b. an acetabular cup that includes a load bearing portion and can embrace a femur cup or a ball head, wherein the acetabular cup comprises cross-linked UHMWPE, wherein the thickness of the cross-linked UHMWPE of the acetabular cup is greater than about 1 mm, and wherein the acetabular cup or the femur cup can accommodate a ball head having a diameter greater than about 35 mm which has a radius of curvature complementary to the cavity in the acetabular cup or the femur cup.
90. (new) A kit comprising a prosthesis assembly of claim 42.
91. (new) A kit comprising a prosthesis assembly of claim 79.
92. (new) A kit comprising a prosthesis assembly of claim 89.
93. (new) A method of implanting a hip joint prosthesis comprising:
  - a. determining socket size; and

- b. implanting a prosthesis of claim 42.

94. (new) A method of implanting a hip joint prosthesis comprising:

- a. determining socket size; and
- b. implanting a prosthesis of claim 79.

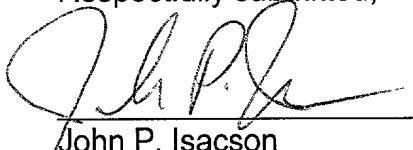
95. (new) A method of implanting a hip joint prosthesis comprising:

- a. determining socket size; and
- b. implanting a prosthesis of claim 89.

**Remarks**

By the foregoing, claims 1 and 37-95 are pending. An Office Action on the merits is now awaited. Should there be any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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